

3525 NORTH REGAL STREET
SPOKANE, WASHINGTON 99207
WWW.HOLLISTER-STIER.COM

509.489.5656 FAX: 509.484.4320



HollisterStier
LABORATORIES LLC

January 7, 2008

URGENT DRUG RECALL

Hollister-Stier Laboratories is issuing a recall for the following Allergenic Extract, Hymenoptera Venom Product:

White-Faced Hornet
Venom Protein
Item Code: 6782UX
Multidose 13.0 mL (1300MCG per Vial, 12 Dose)
Lot No. 1132101C
Exp. Date 06/18/2010

Our records indicate that your office received XXX vials of the product manufactured by Hollister-Stier. Product is being voluntarily recalled because the incorrect overseal was used. The incorrect overseal states "Flip off/Tear off." This overseal can be fully removed, which may potentially compromise the stopper and vial container closure system. If the stopper is removed sterility of the product is no longer assured.

The correct overseal for this product would have stated "Flip off".

We have included a "recall response form" which must be completed by your office, and returned to us via facsimile at (509) 484-4320 or returned to us by mail if you do not have a fax machine.

Also enclosed is a Federal Express air bill to use when returning the product to us. When the vial is ready, please contact Federal Express at 1-800-463-3339 to arrange for them to pick up the product.

This recall is being made with the knowledge of the Food and Drug Administration. A representative of the Agency may contact you to confirm compliance with the program outlined in the letter.

Because of the urgent nature of this recall and the critical use of the product involved, strict compliance is requested. As a health care professional, you are an important Hollister-Stier customer. We apologize for the inconvenience and appreciate your immediate assistance and reply to this request. If you have any questions or need further assistance, please call Customer Service at 1-800-225-6443.

Hollister-Stier Laboratories LLC

Enclosures



RECALL RESPONSE FORM

Please Complete and Fax to 1-509-484-4320

TO: Hollister-Stier Laboratories LLC
3525 N Regal St
Spokane WA 99207-5788
USA

ATTN: Recall Coordinator

RE: **Recall of the Following Venom Product(s):**
Lot 1132101C White Faced Hornet
Item #: 6782UX
Item Description: MULTIDOSE VENOM 1300MCG 12DOSE

Shipment Information:

Venom Lot(s)

- We do not have any of the recalled product remaining.
- We are returning _____ vial(s) of lot 1132101C

FROM:

Acct#

Signature _____

Date _____

Title _____

Phone Number _____

**THIS IS YOUR AUTHORIZATION
TO RETURN MERCHANDISE**

**PLEASE DETACH AND USE
THIS LABEL ON PACKAGE** 

- Include Bottom Part of This Copy with Merchandise inside package.
- Check box in Comments section to request Replacement or Credit for returned product

FROM	
AUTHORIZED RETURN	
 TO	Recall Coordinator Hollister-Stier Laboratories LLC 3525 N. Regal Spokane, WA 99207
CONTENTS: MERCHANDISE - RETURN REQUESTED	

			RECALL			
DATE	SHIP DATE FROM H-S	RETURN AUTHORIZED BY	CREDIT	EXCHANGE	OTHER	SHIP VIA
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ORIG. CUST. P.O. #		OUR INVOICE #				

ITEM NO.	QUANTITY	ITEM / INVENTORY # (include Conc., etc.)	LOT #	REASON RETURNED

<p>COMMENTS:</p> <p><input type="checkbox"/> Replace returned product</p> <p><input type="checkbox"/> Credit account for returned product</p>	
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